



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,449	02/28/2002	Michael L. Blomquist	14485.0141US01	9068

23552 7590 05/12/2010  
MERCHANT & GOULD PC  
P.O. BOX 2903  
MINNEAPOLIS, MN 55402-0903

EXAMINER
----------

NORTON, JENNIFER L

ART UNIT	PAPER NUMBER
----------	--------------

2121

MAIL DATE	DELIVERY MODE
-----------	---------------

05/12/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/087,449	<b>Applicant(s)</b> BLOMQUIST, MICHAEL L.	
	<b>Examiner</b> JENNIFER L. NORTON	<b>Art Unit</b> 2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. The following is a Non-Final Office Action in response to the Amendment/Remarks received on 03 February 2010. Claims 2-9, 11, 14-17 and 21-25 have been amended. Claims 1-25 are pending in this application.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2003/0114836 A1 (hereinafter Estes) in view of U.S. Patent Publication No. 2003/0069650 A1 (hereinafter Karmiy).

4. As per claim 1, Estes teaches a method of programming an ambulatory infusion pump (Fig. 1, element 100) from a computer (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the ambulatory infusion pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program being driven by operating parameters (pg. 3, par. [0032] and [0033]), the method comprising:

generating data (Fig. 3A, element 300) on an interface displayed by the computer the computer having a computer peripheral (col. 6, par. [0054]), the data

(Fig. 3A) contained in a row (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), and different operating parameter for the delivery program (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3); and

downloading the operating parameters into the pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

Estes teaches a user interface displayed (Fig. 3B-3D) by the computer the computer having a computer peripheral (pgs. 2-3, par. [0027] and pg. 6, par. [0056]) but does not expressly teach generating a table on a user interface displayed by the computer the computer having a computer peripheral, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program; entering an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral.

Karmiy teaches to generating a table (Fig. 3; i.e. a spreadsheet including row and columns) on a user interface (Fig. 1, element 104 and 106) displayed by the computer (Fig. 2, par. [0025] and pg. 3, par. [0028]) the computer having a computer peripheral (i.e. 8, par. [0078], [0079] and [0086]; i.e. an input device to provide a user with the ability to enter data/information into cells of the table), the table containing a

row (Fig. 3, element 302a-302g), the row having a plurality of cells (Fig. 3, element 304a-304j), each cell in the row relating to a different operating parameter for the delivery program (Fig. 3, element 304h and 304i); and

entering an operating parameter into at least one of the cells in the table (pg. 8, par. [0086], the operating parameter being entered directly into the at least one of the cells through the computer peripheral (pg. 8, par. [0078] and [0079])).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include generating a table on a user interface displayed by the computer, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program; and entering an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079])).

5. As per claim 8, Estes teaches a method of operating a pump (Fig. 1, element 100), the pump having a memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) and a pump mechanism (pg. 3, par. [0029]), the method comprising:

receiving from a computer, a plurality of data sets, each data set in the plurality of data sets containing a plurality of operating parameters (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage"),

storing the plurality of data sets in memory (pgs. 3-4, par. [0035] and Fig. 1, element 106);

selecting one of the plurality of data sets (pg. 8, par. [0008]) and Fig. 6, i.e. SUSPEND, BOLUS, BASAL); and

running a delivery program wherein the delivery program executes the operating parameters in the selected one of the plurality of data sets, the operating parameters defining a delivery schedule for controlling the pump mechanism (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes does not expressly teach wherein each data set in the plurality of data sets contains the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter.

Karmiy teaches wherein each data set in the plurality of data sets (pg. 3, par. [0028] and Fig. 3, element 302a-302g) comprising the same type of operating parameters (pg. 3, par. [0034] and [0035] and Fig. 3, element 304h and 304i; i.e. an alarm value and engineering units) and at least two of the data sets contain different values for the same type of operating parameter (pg. 3, par. [0035] and Fig. 3, element 304h).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include wherein data sets comprising the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

6. As per claim 9, Estes teaches an apparatus (Fig. 2, element 132) for programming an infusion pump (pgs. 2-3, par. [0027]), pgs. 3-4, par. [0034] and [0035] and Fig. 1, element 100), the pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program programmed to process operating parameters (pg. 3, par. [0032] and [0033]), the operating parameters defining operation of the pump (pg. 6, par. [0054]; i.e. corresponding operating parameters and

Art Unit: 2121

cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), the apparatus comprising:

a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop);

a data entry device (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop); and

a processor in data communication with the data port and the data entry device (pg. 3, par. [0034]; e.g. PC, laptop),

data (Fig. 3A, element 300), the data contained in a row, the row having a plurality of cells (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), each cell in the row relating to a different operating parameter for the delivery program (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3);

(b) display the data in one or more of the cells (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300); and

(c) download the received operating parameters displayed (col. 6, par. [0054]) in the cells to the infusion pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

Estes does not expressly teach the processor programmed to generate a table; and receiving at least one operating parameter directly from the data entry device to the one or more cells.



Karmiy teaches to a processor (Fig. 1, element 102) programmed to generate a table (pg. 2, par. [0025] and pg. 3, par. [0028]; via Fig. 1, element 104 and 106); and receiving at least one operating parameter directly from the data entry device to the one or more cells (pg. 8, par. [0086], the operating parameter being entered directly into the at least one of the cells through the computer peripheral (pg. 8, par. [0078] and [0079]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a processor programmed to generate a table; and receiving at least one operating parameter directly from the data entry device to the one or more cells to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

7. Claims 2-7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes in view of Karmiy in further view of U.S. Patent Publication No. 2003/0011646 A1 (hereinafter Levine).

8. As per claim 2, Estes teaches the table comprising a plurality of rows (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3).

Estes does not expressly teach each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump.

Karmiy teaches to each row (pg. 2, par. [0029] and Fig. 3, element 302a-302g) relating to a different set of operating parameters (pg. 2, par. [0034] and [0035] and Fig. 3, element 304h and 304i), each set of operating parameters defining a different operation for the device (pg. 2, par. [0029]).

Karmiy does not expressly teach each set of parameters defining a different delivery schedule.

Levine teaches different sets of parameters (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. dosage and frequency amount of a medication), each set of parameters defining a different delivery schedule (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. each row represents individual medications, and dosages and frequency amounts of each individual medication).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include each row relating to a different set of operating parameters, each set of operating parameters defining a different operation for the device to provide enhanced control of the delivery of a medication over a period of time with precision and in a automated manner,

without significant restriction on the user's mobility or lifestyle (Karmiy: pg. 1, par. [0007] and [0008]); and different sets of parameters, each set of parameters defining a different delivery schedule to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (Levine: pg. 1, par. [0009]).

9. As per claim 3, Estes teaches as set forth above the table comprising at least one cell within each row relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "at least one cell within each row relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name" as follows:

As per claim 3, Estes teaches to a method substantially the same as claimed but does not expressly teach one cell within each row is relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Karmiy teaches one cell within each row relating to a unique identifying name (pg. 3, par. [0032] and Fig. 3, element 304g) wherein the unique identifying name

Art Unit: 2121

identifies the parameters of the identifying name (pg. 3, par. [0034] and [0035] and Fig. 3, element 304h and 304i).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include one cell within each row relating to a unique identifying name wherein the unique identifying name identifies the parameters of the identifying name to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

10. As per claim 4, Estes teaches as set forth above downloading the operating parameters into memory (Fig. 2, element 106) on the pump (pgs. 3-4, par. [0035]; downloading the operating parameters from Fig. 2, element 132), the pump being programmed with a delivery schedule (pgs. 3-4, par. [0035]).

11. As per claim 5, Estes teaches as set forth above running the delivery program and, executing the operating parameters (pg. 8, par. [0073] and Fig. 6).

12. As per claim 6, Estes teaches as set forth above the method further comprising:  
downloading all of the operating parameters to the infusion pump (pgs. 3-4, par. [0035] and Figs. 3A, element 300); and

storing the operating parameters in the memory (pgs. 3-4, par. [0035]).

13. As per claim 7, Estes teaches as set forth above selecting one unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program and executing at least some of the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "selecting one unique identifying and running the delivery program and executing at least some of the operating parameters identified by the selected unique identifying name" as follows:

As per claim 7, Estes teaches to selecting one identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program and executing at least some of the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

Estes does not expressly teach to a unique identifying name; and the operating parameters identified by the selected unique identifying name.

Karmiy teaches a unique identifying name (pg. 3, par. [0032] and Fig. 3, element 304g); and the operating parameters identified by the selected unique identifying name (pg. 3, par. [0034] and [0035] and Fig. 3, element 304h and 304i).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a unique identifying name; and the operating parameters identified by the selected unique identifying name to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

14. As per claim 10, Estes teaches the processor is further programmed to generate a plurality of rows in the table rows (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3).

Estes does not expressly teach each row relating to a different set of operating parameter, each set of operating parameters defining a different delivery schedule for the pump.

Karmiy teaches to each row (pg. 2, par. [0029] and Fig. 3, element 302a-302g) relating to a different set of operating parameters (pg. 2, par. [0034] and [0035] and Fig. 3, element 304h and 304i), each set of operating parameters defining a different operation for the device (pg. 2, par. [0029]).

Karmiy does not expressly teach each set of parameters defining a different delivery schedule.

Levine teaches different sets of parameters (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. dosage and frequency amount of a medication), each set of parameters defining a different delivery schedule (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. each row represents individual medications, and dosages and frequency amounts of each individual medication).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include each row relating to a different set of operating parameters, each set of operating parameters defining a different operation for the device to provide enhanced control of the delivery of a medication over a period of time with precision and in a automated manner, without significant restriction on the user's mobility or lifestyle (Karmiy: pg. 1, par. [0007] and [0008]); and different sets of parameters, each set of parameters defining a different delivery schedule to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (Levine: pg. 1, par. [0009]).

15. As per claim 11, Estes teaches as set forth above each row in the table includes at least one cell relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach “each row in the table includes at least one cell relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name” as follows:

As per claim 11, Estes teaches to a method substantially the same as claimed but does not expressly teach each row in the table includes at least one cell relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Karmiy teaches each row in the table includes at least one cell relating to a unique identifying name (pg. 3, par. [0032] and Fig. 3, element 304g), wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 3, par. [0034] and [0035] and Fig. 3, element 304h and 304i).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant’s invention to modify the teaching of Estes to include each row in the table includes at least one cell relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name to provide an improved and efficient techniques for generating



instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

16. Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes in view of U.S. Patent No. 5,814,015 (hereinafter Gargano) in further view of U.S. Patent No. 5,719,761 (hereinafter Gatti).

17. As per claim 12, Estes teaches a method of operating an infusion pump (Fig. 1, element 100) for delivering a therapeutic agent into the body of a user (pg. 3, par. [0029]), the infusion pump being programmable (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132) and including memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), the infusion pump being programmed to run a delivery program (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the delivery program controlling the infusion pump to deliver the therapeutic agent according to a delivery schedule (pg. 3, par. [0032]-[0034], pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY), the method comprising:

storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

running the delivery program (pg. 8, par. [0073] and Fig. 6), the delivery program executing the set of operating parameters thereby controlling the infusion pump to deliver the therapeutic agent according to the delivery schedule defined by the set of operating parameters (pg. 6, par. [0057] and [0059]).

Estes teaches to a method substantially the same as claimed but does not expressly teach selecting one user-defined identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected user-defined identifying name (pg. 6, par. [0057] and [0059]).

Gargano teaches to a field for the selection of an identifying a name (col. 11, lines 40-47; i.e. the "drug name"); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected identifying name (col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Gargano does not expressly teach to a user-defined identifying name.

Gatti teaches to a user-defined identifying name for an infusion pump (col. 8, lines 30-39).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a field for

Art Unit: 2121

the selection of an identifying a name; and running the delivery program wherein the delivery program executes the operating parameters identified by the selected identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and a user-defined identifying name for an infusion pump to provide unique identifying name to a new configuration to avoid having mix of configurations with the same name (Gatti: col. 8, lines 40-44).

18. As per claim 13, Estes teaches as set forth above downloading the data set to the pump from a computer (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

19. As per claim 14, Estes teaches as set forth above the act of storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) further comprising storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these

Art Unit: 2121

events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage”).

20. As per claim 15, Estes teaches as set forth above to generating a menu, the menu including at least one menu item corresponding to one of the user-defined identifying names; and the act of selecting the user-defined identifying name further comprising selecting the menu item (pg. 8, par. [0073] and Fig. 6, element “Main Menu”).

21. As per claim 16, Estes teaches as set forth above the act of storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) further comprising storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) includes storing a plurality of data sets in memory, each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., “The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user”; pg. 7, [0063], i.e., “the time change is displayed in either 12 or 24 hr format depending on user’s settings”; pg. 7, par. [0064], i.e., “At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage”).

22. As per claim 17, Estes teaches as set forth above to generating a menu includes generating a menu having at least one menu item corresponding to a user-defined identifying name from one data set and at least one menu item corresponding to a user-defined identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

23. As per claim 18, Estes teaches as set forth above to the execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pg. 8, par. [0074]).

24. As per claim 19, Estes teaches an infusion pump (pgs. 2-3, par. [0027] and Fig. 1, element 100) comprising:

- a pump mechanism (pg. 3, par. [0029]);

- memory storing a data set (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

- a processor (pg. 3, par. [0034]; e.g. PC, laptop) arranged to control the pump mechanism and in data communication with the memory (pgs. 3-4, par. [0034]), the processor being programmed to assign the set of operating parameters (pg. 6, par.

Art Unit: 2121

[0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3) to the delivery program (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY) and to execute the set of operating parameters thereby controlling the pump mechanism to deliver the therapeutic agent according to the delivery schedule (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes teaches to a method substantially the same as claimed but does not expressly teach the delivery program upon selection of the user-defined identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Gargano teaches the delivery program upon selection of the identifying name (col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Gargano does not expressly teach to a user-defined identifying name.

Gatti teaches to a user-defined identifying name for an infusion pump (col. 8, lines 30-39).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include the delivery program upon selection of the identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and a user-defined identifying name for an infusion pump to provide

Art Unit: 2121

unique identifying name to a new configuration to avoid having mix of configurations with the same name (Gatti: col. 8, lines 40-44).

25. As per claim 20, Estes teaches set forth above a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop), the processor being further arranged to control downloading of the data set and storage of the data set into the memory (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

26. As per claim 21, Estes teaches as set forth above the memory further storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100,132; 0035, lines 1-7; Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; [0064], lines 13-15, i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

27. As per claim 22, Estes teaches as set forth above the processor being further programmed to:

generate a menu, the menu including at least one menu item corresponding to one of the unique identifying names, selecting the menu item being at least one step in beginning execution of the delivery program (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

28. As per claim 23, Estes teaches as set forth above the memory further storing two or more data sets (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

29. As per claim 24, Estes teaches as set forth above the processor being further programmed to generate a menu, the menu including at least one menu item corresponding to a user-defined identifying name from one data set and at least one user-defined identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element "Main Menu").



Art Unit: 2121

30. As per claim 25, Estes teaches as set forth above the processor being further programmed to switch execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pg. 8, par. [0074]).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited to further show the state of the art with respect to medical management systems.

European Patent Application No. 0 319 272 A2 discloses a hardware portion of the user interface consists of an audio signal generator, status indicators, an information display and user input controls (20).

European Patent Application No. 0 503 670 A2 discloses a pump has a message display, a storage section, a setting section and an operation section.

U.S. Patent No. 5,772,635 discloses a medication infusion system having an integrated dose rate calculation feature for selectively assigning values to a plurality of infusion parameters and automatically calculating an infusion rate from the selected parameters.

U.S. Patent No. 6,012,034 discloses a computer system comprising a control program stored in a memory recommends an intravenous device for infusion therapy based on input entered by a user.

U.S. Patent No. 6,671,563 B1 discloses a care management system in which the management of the administration of care for patients is automated.

U.S. Patent No. 6,749,586 B2 discloses a remotely programmable infusion system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. NORTON whose telephone number is (571)272-3694. The examiner can normally be reached on Monday-Friday between 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert Decady can be reached on 571-272-3819. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Art Unit: 2121

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Albert DeCady/  
Supervisory Patent Examiner  
Art Unit 2121

/JLN/